GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4192
ANSWERED ON:11.08.2017
Manufacturing of Generic Drugs
Patle Smt. Kamla Devi

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether India is the biggest manufacturer and exporter of generic drugs in the world and if so, the details thereof;

(b) whether the Government has fixed any uniform procedure for issuing license to manufacturers of generic drugs in the country;

(c) the State-wise details of companies which have been issued such licenses; and

(d) the steps taken/proposed to be taken by the Government to protect the interest of such generic drug manufacturers from multinational pharmaceutical companies?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a): Yes. India is one of the largest manufacturers and exporters of generic medicines in the world. The details of India's exports of generic medicines are as below:

India's exports in US mn
Year 2014-15 2015-16 2016-2017
Formulations (Generic Medicines) 11214 12646 12701

(b): The manufacture for sale of any drug in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder. Licenses for manufacture of sale are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. Requirements for grant of such licences are prescribed under the said Act and Rules which are required to be followed uniformly across the country.

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(c): As stated in (b) above, manufacturing license is granted by State Licensing Authority. Data in this regard is not maintained centrally.
(d): The Medical Council of India (MCI) has amended its code providing for generic prescription by the doctors. Further, Department of Pharmaceuticals is operating a Scheme 'Pradhan Mantri Bharatiya Janaushadhi Pariyojana' (PMBJP) in which quality generic medicines are being made available to the Indian masses at affordable price.
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